

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of : Pairet, M. et al ) Art Unit: 1615  
U.S. Appln. No. : To Be Accorded ) Examiner: Humera N. Sheikh  
Confirmation No. : To Be Accorded  
U.S. Filing Date : 04/14/2004  
Title of Invention : Pharmaceutical Compositions Containing Tiotropium Salts And  
Antihistamines And Their Use  
Attny. Docket No.: 1/1244-1-C1

Mail Stop Patent Application  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

April 14, 2004

**TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents listed herein and on the attached PTO-1449 form and which the Examiner may deem relevant to patentability of the claims of the above-identified application. Copies of the citations listed on the PTO-1449 form are filed in US Application No. 10/007,182, filed on October 19, 2001, Pairet, M. et al (Attorney Docket No. 1/1244).

☒ 1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 33 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

☐ 1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

☐ A statement as specified in 37 C.F.R. §1.97(e) [see below]; or

☐ The fee set forth in 37 C.F.R. §1.17(p).

☐ The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

☐ 1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).

☐ 1.97(e).

☐ Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or

☐ No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.

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☐ 1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.

☒ The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Triplicate copies of this form are enclosed.

Respectfully submitted,

*Michael P. Morris*

Michael P. Morris  
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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2

**Complete if Known**

Application Number	To Be Accorded
Filing Date	04/14/2004
First Named Inventor	Michel PAIRET
Art Unit	1615
Examiner Name	Humera N. SHEIKH
Attorney Docket Number	1/1244-1-C1

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 5,824,669 A	10/29/1998	Garvey, et al	
		US- 6,284,287 B1	09/2001	Sarlikiotis, et al	
		US- 5,824,669	10/1998	Garvey, et al	
		US- 4,042,700	08/16/1977	Banholzer, R. et al	
		US- 4,608,377	08/26/1986	Banholzer, R. et al	
		US- 4,783,534	10/08/1998	Banholzer, R. et al	
		US- 5,610,163	03/11/1997	Banholzer, R. et al	
		US- 5,654,314	08/05/1997	Banholzer, R. et al	
		US- 5,770,738	06/23/1998	Banholzer, R. et al	
		US- 5,952,505	09/14/1999	Banholzer, R. et al	
		US- 6,486,321	11/26/2002	Banholzer, R. et al	
		US- 6,506,900	01/14/2003	Banholzer, R. et al	
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		US-			
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		WO 97/46243 A	12/11/1997	Procter & Gamble		
		DE 42 03 306 A	08/12/1993	IG Spruehtechnik		
		WO 98/41256 A	09/24/1998	Astra Aktiebolag		

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete If Known</b>			
				Application Number		To Be Accorded	
				Filing Date		04/14/2004	
				First Named Inventor		Michel PAIRET	
				Art Unit		1615	
				Examiner Name		Humera N. SHEIKH	
Sheet	2	of	2	Attorney Docket Number		1/1244-1-C1	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		NACLERIO, R. M.; "Optimizing Treatment Options"; Clinical and Experimental Allergy, Bd. 28, Nr. Suppl. 6, 1998, 54-59	
		SIMONS, ET AL; "Optimum Pharmacological management of Chronic Rhinitis";, Drugs, Bd. 38, Nr. 2, 1989, 313-331	
		MON, ET AL; "Aerosol Therapy in Asthma"; Revue Des Maladies Respiratoires, Bd. 6, Nr. 3, 1989, 189-200	
		PAVIA, ET AL; "Preliminary Data From Phase II Studies With Respimat, A Propellant-Free Soft Mist Inhaler"; J. of Aerosol Medicine: the Official J. of the Int'l Soc. for Aerosols in Medicine. US 1999, Bd. 12, Suppl. 1, 1999, S33-S39	
		Patent Abstracts of Japan; Vol. 1999, No. 02, 02/26/1999 & JP 10 298107 A, Taisho Pharm. Co., 11/10/1998	
		U.S. Patent Application Publication No. 2002/0137764 Published September 26, 2002 - Inhalable Formulation of a Solution Containing a Tiotropium Salt, Drechsel, K. et al	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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